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Patrea L Pabst
Arnall Golden & Gregory LLP
2800 One Atlantic Center
1201 West Peachtree Street
Atlanta, GA 30309-3450

EXAMINER	
GABEL, GAILENE	
ART UNIT	PAPER NUMBER
1641	12

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/526,582	Applicant(s) FITZPATRICK ET AL.	
	Examin r Gailene R. Gabel	Art Unit 1641	

-- The MAILING DATE of this communication appears n the c ver sheet with the corresp ndence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 26 November 2001 .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-23 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-23 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Amendment Entry

1. Applicant's amendment and response filed 11/26/01 in Paper No. 10 is acknowledged and has been entered. Claims 1, 4, 6, 9, 12-13, 16, and 18-20 have been amended. Claims 21-23 have been added. Accordingly, claims 1-23 are pending and under examination.

Rejections Withdrawn

2. In light of Applicant's amendment and arguments, the rejection of claims 12, 14, and 16-18 under 35 U.S.C. 102(b) as being anticipated by 1) Oberhardt (US 5,677,133) is, hereby, withdrawn.

3. In light of Applicant's amendment and arguments, the rejection of claims 12, 14, and 16-18 under 35 U.S.C. 102(b) as being anticipated by 2) Oberhardt (US 5,601,991) is, hereby, withdrawn.

4. In light of Applicant's amendment, the rejection of claims 16 and 18 under 35 U.S.C. 102(b) as being anticipated by Ullman et al. (US 5,137,808) is, hereby, withdrawn.

5. In light of Applicant's amendment, the rejection of claims 16 and 18 under 35 U.S.C. 102(b) as being anticipated by Kang (US 5,559,041) is, hereby, withdrawn.

6. In light of Applicant's amendment, the rejection of claims 16 and 18 under 35 U.S.C. 102(b) as being anticipated by Chen et al. (US 5,384,264) is, hereby, withdrawn.

7. In light of Applicant's amendment, the rejection of claims 16 and 18 under 35 U.S.C. 102(b) as being anticipated by May et al. (US 5,602,040) is, hereby, withdrawn.

8. In light of Applicant's amendment, the rejection of claim 19 under 35 U.S.C. 103(a) as being unpatentable over Coppo et al. (Journal of Diabetic Complications, 1987 (Abstract)) in view of Kang (US 5,559,041) or Chen et al. (US 5,384,264) or May et al. (US 5,602,040) or Ullman et al. (US 5,137,808) is, hereby, withdrawn.

Rejections Maintained

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-11, 16, and 20-23 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is ambiguous in reciting, "detecting the amount of immunoreactivity ...comparing the amount of immunoreactivity" because it is unclear how "immunoreactivity" equates with the level, i.e. concentration, of apolipoprotein being determined as recited in the preamble. Specifically, the term "reactivity" refers to a capacity to react / bind while the level of apolipoprotein to be determined, as required by the preamble appears to refer to an amount / concentration of apolipoprotein. Please clarify. Further, claim 1 is indefinite in reciting, "reacting the saliva with antibodies"

because it appears that the antibodies are immunoreactive only with apolipoprotein contained in the saliva.

Claim 5 is indefinite and lacks clear antecedent support in reciting, "the saliva is tested" because it is unclear what is encompassed by the term "tested" in relation to amended claim 1 from which it depends. Perhaps, Applicant intends, "... further comprising, determining the level of apolipoprotein in the saliva within less than three hours ..."

Claim 6 is indefinite and lacks clear antecedent support in reciting, "the saliva is prepared prior to testing" because it is unclear what is encompassed by the term "prepared prior to testing" in relation to amended claim 1 from which it depends. Perhaps, Applicant intends, "... further comprising, preparing the saliva by removing mucopolysaccharides prior to determining the level of apolipoprotein in the saliva".

Claim 7 remains ambiguous in reciting "saliva is collected after stimulation" because it appears that the saliva itself, is being stimulated, whereas it is the secretion of saliva from the salivary glands that is being stimulated, i.e. using lemon and breath mints (see specification at page 18). Perhaps, Applicant intends, "... further comprising, collecting the saliva after stimulating its secretion from a subject".

Claim 9 is ambiguous in reciting "normalizing the amount of apolipoprotein to the amount of albumin present" because it is unclear what Applicant intends to encompass in reciting, "normalizing" as used in the claim. For example, does Applicant intend to correct for the presence of albumin to reflect an accurate level of apolipoprotein?

Specifically, claim 9 fails to distinctly define how the existence of albumin relates and affects the apolipoproteins recited in claim 1 from which it depends.

Claim 9 lacks antecedent support in reciting "the individual from whom the saliva was obtained".

Claim 10 has improper antecedent basis problems in reciting, "antibodies" and "apolipoproteins". Change to "said antibodies" and "the apolipoproteins" for proper antecedent basis.

Claim 16 lacks clear antecedent support in reciting, "the antibodies", i.e. capture, apolipoprotein specific, albumin specific.

Claim 20 is incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. Specifically, claim 20 fails to recite: 1) a detecting step that enables quantitation of the amount of lipoprotein as required by the preamble and 2) a determining step or correlating step that enables determination of the presence of lipid disorders or risk of cardiovascular disease in a patient. Claim 20 further fails to establish how the amount of lipoprotein or cholesterol correlates with the presence of lipid disorders or risk of cardiovascular disease in the patient. Claim 20 is vague and indefinite in reciting, "reacting the saliva with antibodies" because it appears that the antibodies are immunoreactive only with apolipoprotein contained in the saliva.

Same analogous comments and problems in claim 20 apply to claim 22.

Claim 21 is ambiguous because it is unclear what Applicant intends to encompass in reciting, "determining a correlation between". It appears that Applicant

should intend to set forth a "correlation step" to correlate the levels of HLD or LDL and the levels of apolipoproteins instead.

Claim 21 is confusing because it is unclear what Applicant intends to encompass in reciting, "determining the levels of HDL and/or LDL based on the measurements of the levels of the apolipoproteins in the saliva". Specifically, claim 21 fails to distinctly define how the levels of apolipoproteins in the saliva relate with the levels of HDL and/or LDL so as to be able to perform this instant step.

Claim 21 lacks antecedent support in reciting, "the levels of HDL and/or LDL".

Claim 21 is indefinite in reciting, "HDL and LDL". Acronyms or abbreviations must be recited at least one time in a set of claims.

In claim 21, "and/or" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention.

Claim 22 is indefinite in reciting, "correlating the levels ..." because it fails to distinctly define how the level of at least one apolipoprotein correlates with the levels in the serum and with the presence of lipid disorders or risk of cardiovascular disease in the patient.

In claim 22, it is unclear what Applicant intends to encompassed in reciting, "associated with".

Claim 23 lacks antecedent support in reciting, "the measurements of the apolipoproteins in the serum, since claim 1 is drawn to detecting levels of lipoproteins in the saliva.

Claim 23 is confusing in reciting, "the measurements of the apolipoproteins in the serum are normalized against the level of albumin in the saliva as compared to the level of albumin in the serum from the individual". It is unclear what Applicant is intending to encompass because the limitations set forth does not seem decipherable in itself or in relation to claim 20 from which it depends. Please clarify.

Claim Rejections - 35 USC § 102

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-3 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by 1) Oberhardt (US 5,677,133) for reason of record.

11. Claims 1-3 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by 2) Oberhardt (US 5,601,991) for reason of record.

12. Claims 1, 2, and 4 are rejected under 35 U.S.C. 102(e) as being anticipated by Kundu et al. (US 6,210,906) for reason of record.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

> invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 5-7,10-14, and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over 1) Oberhardt (US 5,677,133) or 2) Oberhardt (US 5,601,991) in view of Fellman et al. (US 5,112,758).

Specifically, 1) Oberhardt et al. disclose a kit or system comprising a strip or dipstick (reaction slide) having a dry reagent which includes antibodies immunoreactive to an analyte of interest, i.e. apolipoproteins. The kit also includes buffers and neutralizers. (See column 20). Specifically, 2) Oberhardt et al. disclose a kit or system comprising a strip or dipstick (reaction slide) having a dry reagent which includes antibodies immunoreactive to an analyte of interest, i.e. apolipoproteins. The kit also includes buffers and neutralizers. (See column 23).

Oberhardt or Oberhardt differ in failing to disclose a means for collecting saliva.

Fellman et al. disclose a method and kit for stimulating saliva production (inducing salivation) in a subject using a sour stick (ascorbic acid) (see column 3, lines

45-61). Fellman et al. also teach treating saliva prior to diagnostic testing using cationic quaternary ammonium reagents. Specifically, Fellman et al. disclose that centrifuge and filters are known techniques for removing mucopolysaccharides from saliva. According to Fellman et al., viscosity reduction is necessary for the preparation of body fluids containing mucopolysaccharides for accuracy in testing, i.e. detecting for presence of antibodies and antigen (see column 1 and 4).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate the teaching of Fellman in removing mucopolysaccharides to reduce viscosity of a specimen into the method and kit taught by 1) Oberhardt and 2) Oberhardt in detecting apolipoproteins in the saliva because Fellman specifically taught that removal of this excess element decreases background noise which prevents useful and accurate detection of analyte such as the apolipoproteins (see Fellman et al., column 3, lines 15-25).

14. Claims 7-9, 12, 14-18, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oberhardt (US 5,677,133) or Oberhardt (US 5,601,991) in view of Fisher et al. (Diabetes Research and Clinical Practice, 1991) and Coppo et al. (Journal of Diabetic Complications, 1987).

1) Oberhardt and 2) Oberhardt have been discussed supra.

1) Oberhardt and 2) Oberhardt differ in failing to teach means for determining the amount of albumin in the saliva and means for normalizing the amount of apolipoprotein to the amount of albumin present in the saliva. 1) Oberhardt and 2) Oberhardt further

differ in failing to teach antibodies immunoreactive to albumin in the device or kit for determining apolipoprotein concentration.

Specifically, Fisher et al. teach using citric acid to stimulate saliva secretion then measuring its albumin level using ELISA kit and method. Fisher et al. compare albumin concentration between saliva and urine in diabetes patients.

Coppo et al. teach determining urinary albumin concentrations using anti-albumin antibody in an indirect ELISA kit and technique.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate the teaching of Coppo in using anti-albumin antibodies to measure the level of albumin in a body fluid such as urine using ELISA technique or saliva such as in the ELISA method taught by Fisher, into the method and device taught by 1) Oberhardt or 2) Oberhardt because 1) Oberhardt and 2) Oberhardt specifically suggested application of their kit and method in multianalyte or panel screening applications for any antigen combination present in body fluids, such as apolipoproteins and albumin present in saliva, using respective immunoreactive antibodies that are specific thereto. Further, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate the reagents, labels and immunoreactive antibodies specific for albumin in the method taught by Coppo into a kit arrangement because test kits are conventional and well known in the art for their recognized advantages of convenience and economy.

It further would have been prima facie obvious to one of ordinary skill in the art to perform statistical evaluation of concentration levels between coexisting analytes

present in a body fluid and effect correction, if necessary, to remove effects of possible interference or dilution, so that an actual concentration of the desired analyte is obtained since statistical correction methods are standard in laboratory practice during optimization procedures.

15. Claims 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oberhardt (US 5,677,133) or Oberhardt (US 5,601,991) in view of Schneider (US 6,291,178).

1) Oberhardt and 2) Oberhardt have been discussed supra.

1) Oberhardt and 2) Oberhardt differ from the instant invention in failing to teach correlating lipoprotein levels between serum sample and the saliva.

Schneider discloses a method and apparatus for collecting saliva for use in assaying for the presence of biologics such as lipoproteins and cholesterol. According to Schneider, biologics such as lipoproteins, cholesterol, including (blood) alcohol, which are present in the blood plasma are also found to be present in the saliva. Schneider also discloses that correlations between saliva and blood plasma levels are deduced using known protocols in the art, i.e. A. W. Jones, Clin. Chem. (1993) Vol. 39(9): 1837-1843 (see column 2, line 45 to column 3, line 11 and also column 4, lines 24-65).

One of ordinary skill in the art at the time of the instant invention would have been motivated to incorporate the teaching of Schneider in correlating saliva levels of lipoprotein and cholesterol with their levels in the blood, into the method taught by the

Oberhardt patents in determining apolipoprotein levels because Schneider specifically taught that knowledge of correlative equivalence of analyte values in saliva in relation to blood levels provides the advantage of utilizing non-invasive procedure in determining analyte concentration in a patient by collecting saliva rather than drawing blood from the patient.

16. Claims 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Oberhardt (US 5,677,133) or Oberhardt (US 5,601,991) in view of Fisher et al. (Diabetes Research and Clinical Practice, 1991) and Coppo et al. (Journal of Diabetic Complications, 1987) and in further view of Schneider (US 6,291,178).

1) Oberhardt, 2) Oberhardt, Fisher et al. and Coppo et al. have been discussed supra. 1) Oberhardt and 2) Oberhardt Fisher et al. and Coppo et al. differ from the instant invention in failing to teach correlating lipoprotein levels between serum sample and the saliva.

Schneider has been discussed supra.

One of ordinary skill in the art at the time of the instant invention would have been motivated to incorporate the teaching of Schneider in correlating saliva levels of lipoprotein and cholesterol with their levels in the blood, into the method taught by the Oberhardt patents in determining apolipoprotein levels as modified by Fisher and Coppo to remove interfering effects by albumin, because Schneider specifically taught that knowledge of correlative equivalence of analyte values in saliva in relation to blood levels provides the advantage of utilizing non-invasive procedure in determining analyte

concentration in a patient by collecting saliva rather than drawing blood from the patient. Further, it would have been prima facie obvious to one of ordinary skill in the art to perform statistical evaluation of concentration levels between coexisting analytes present in a body fluid and effect correction, if necessary, to remove effects of possible interference or dilution, so that an actual concentration of the desired analyte is obtained since statistical correction methods are standard in laboratory practice during optimization procedures.

Response to Arguments

17. A) Applicant argues that the Oberhardt patents do not teach the detection of apolipoprotein levels in saliva and that neither teach that there is a correlation between levels in the saliva and the blood.

Contrary to Applicant's argument, the Oberhardt patents, indeed, disclose a method for determining the levels of apolipoproteins such as apo-A1 and apo B-100 in a blood sample by adding a sample suspected of having apolipoproteins into a dry reagent containing antibodies immunoreactive to the apolipoproteins.
Both Oberhardt patents also disclose in column 4, lines 11-16 that the method is applicable for use with difficult biological samples including saliva.

In response to applicant's argument that both Oberhardt patents do not teach correlating the levels in the saliva with that in blood, it is noted that this feature is not recited in the rejected claims. Although the claims are interpreted in light of the

specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

B) Applicant argues that the Kundu does not teach how or why the level of apolipoproteins, i.e. apo A should be detected in saliva. Applicant argues that Kundu does not teach that there is a correlation between levels in the saliva and the blood.

Indeed, Kundu discloses detecting apolipoprotein A in a saliva sample by immunoreacting labeled monoclonal antibodies with the Apo A in the sample, specifically against kringle 5 domain of apo A.

In response to applicant's argument that Kundu does not teach correlating the levels in the saliva with that in blood, it is noted that this feature is not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

C) Applicant argues that the Fellman does not suggest detecting apolipoproteins in saliva. Applicant argues that Fellman does not suggest that there is a correlation between levels of apolipoproteins in the saliva and the blood.

In response, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case, Oberhardt patents disclose a method for

determining the levels of apolipoproteins such as apo-A1 and apo B-100 in a blood sample by adding a sample suspected of having apolipoproteins into a dry reagent containing antibodies immunoreactive to the apolipoproteins. Both Oberhardt patents also disclose that the method is applicable for use with difficult biological samples including saliva. Fellman was incorporate thereto for disclosing a method and kit for stimulating saliva production (inducing salivation) in a subject using a sour stick and treating saliva prior to diagnostic testing using cationic quaternary ammonium reagents. Fellman discloses that centrifuge and filters are known techniques for removing mucopolysaccharides from saliva. It would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate the teaching of Fellman in removing mucopolysaccharides to reduce viscosity of a specimen into the method and kit taught by 1) Oberhardt and 2) Oberhardt in detecting apolipoproteins in the saliva because Fellman specifically taught that removal of this excess element decreases background noise which prevents useful and accurate detection of analyte such as the apolipoproteins.

In response to applicant's argument that Fellman does not suggest correlating the levels in the saliva with that in blood, it is noted that this feature is not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

D) Applicant argues that the Fisher and Coppo do not suggest detecting apolipoproteins in saliva. Applicant argues that Fisher and Coppo do not suggest that there is a correlation between levels of apolipoproteins in the saliva and the blood.

In response, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case, Oberhardt patents disclose a method for determining the levels of apolipoproteins such as apo-A1 and apo B-100 in a blood sample by adding a sample suspected of having apolipoproteins into a dry reagent containing antibodies immunoreactive to the apolipoproteins. Both Oberhardt patents also disclose that the method is applicable for use with difficult biological samples including saliva. Fisher and Coppo were incorporated thereto for teaching comparison of albumin concentration between saliva and using and determining urinary albumin concentrations using anti-albumin antibody in an indirect ELISA kit and technique. It would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate the teaching of Coppo in using anti-albumin antibodies to measure the level of albumin in a body fluid such as urine using ELISA technique or saliva such as in the ELISA method taught by Fisher, into the method and device taught by 1) Oberhardt or 2) Oberhardt because 1) Oberhardt and 2) Oberhardt specifically suggested application of their kit and method in multianalyte or panel screening applications for any antigen combination present in body fluids, such as apolipoproteins and albumin present in saliva, using respective immunoreactive antibodies that are

specific thereto. Further, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate the reagents, labels and immunoreactive antibodies specific for albumin in the method taught by Coppo into a kit arrangement because test kits are conventional and well known in the art for their recognized advantages of convenience and economy.

In response to applicant's argument that Fisher and Coppo do not suggest correlating the levels in the saliva with that in blood, it is noted that this feature is not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

18. Applicant's arguments have been considered but are moot in view of the new grounds of rejection.

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (703) 305-0807. The examiner can normally be reached on Monday-Thursday from 6:30 AM - 4:00 PM and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 308-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

BAO-THUY L. NGUYEN
PRIMARY EXAMINER
1/25/02

Gailene R. Gabel
January 25, 2002